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(PATENT)

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Daniel G. Chain

Application No.: 10/084,380

Confirmation No.: 3496

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For: SPECIFIC ANTIBODIES TO AMYLOID BETA

PEPTIDE, PHARMACEUTICAL

COMPOSITIONS AND METHODS OF USE

THEREOF

Examiner: O. N. Chernyshev

# **DECLARATION PURSUANT TO 37 C.F.R. 1.821(f)**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

- I, Mitchell Bernstein, declare as follows:
- 1. That the content of the paper and computer readable copies of the Sequence Listing, submitted in accordance with 37 C.F.R. 1.821(c) and (e), respectively, and PCT Rule 5.2, are the same in compliance with 37 C.F.R. 1.821(f).
- 2. That all statements made herein of my own knowledge are true and that all statements were made on information and belief and are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both,

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Dated: August 10, 2005

Respectfully submitted,

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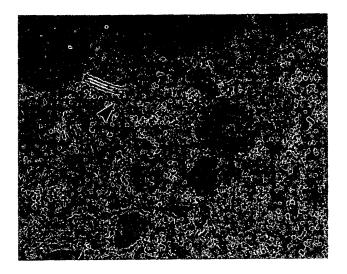
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Birbeck Granules

#### bis-diazotized benzidine

A chemical substance that serves as a bivalent coupling agent which can link to protein molecules. This method was used in the past to conjugate erythrocytes with antigens for use in the passive agglutination test.

CI NN CI NN CI bis-diazotized benzidine

#### bispecific antibodies

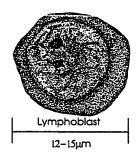
Molecules that have two separate antigen-binding specificities. They may be produced by either cell fusion or chemical techniques. An immunoglobulin molecule in which one of two antigen-binding sites is specific for one antigen-binding specificity, whereas the other antigen-binding site is specific for a different antigen specificity. This never occurs in nature, but it can be produced in vitro by treating two separate antibody specificities with mild reducing agents converting the central disulfide bonds of both antibody molecules to sulfhydryl groups, mixing the two specificities of half molecules together, and allowing them to reoxidize to form whole molecules, some of which will be bispecific.

## BLA-36

An antigen demonstrable by immunoperoxidase staining in Reed-Sternberg cells of all types of Hodgkin's disease and in activated B lymphocytes and B cell lymphomas.

#### blast cell

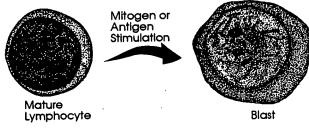
A relatively large cell that is greater than 8 µm in diameter with abundant RNA in the cytoplasm, a nucleus with loosely arranged chromatin and a prominent nucleolus. Blast cells are active in synthesizing DNA and contain numerous polyribosomes in the cytoplasm.



Blast Cell

#### blast transformation

The activation of small lymphocytes to form blast cells.



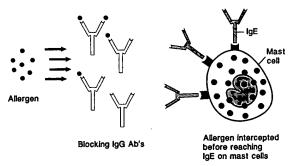
Blastogenesis

#### blocking

Prevention of nonspecific interaction of an antibody with a certain antigenic determinant, whose identification is sought, by washing with mammalian serum other than that being used in the test system. For example, enzyme-linked immunosorbent assays (ELISA) employ blocking.

#### blocking antibody

(1) An incomplete IgG antibody that, when diluted, may combine with red blood cell surface antigens and inhibit agglutination reactions used for erythrocyte antigen identification. This can lead to errors in blood grouping for Rh, K, and k blood types. Pretreatment of red cells with enzymes may correct the problem. (2) An IgG antibody specifically induced by exposure of allergic subjects to specific allergens, to which they are sensitive, in a form that favors IgG rather than IgE production. The IgG, specific for the allergens to which they are sensitized, competes within IgE molecules bound to mast cell surfaces, thereby preventing their degranulation and inhibiting a type I hypersensitivity response. (3) A specific immunoglobulin molecule that may inhibit the combination of a competing antibody molecule with a particular epitope. Blocking antibodies may also interfere with the union of T cell receptors with an epitope for which they are specific, as occurs in some tumor-bearing patients with blocking antibodies which may inhibit the tumoricidal action of cytotoxic T lymphocytes.



**Blocking Antibodies** 

#### blocking factor

Agents such as immune complexes in the serum of tumor-bearing hosts that interfere with the capacity of immune lymphoid cells to mediate cytotoxicity of tumor target cells.

#### blocking test

An assay in which the interaction between an antigen and its homologous antibody is inhibited by the previous exposure of the antigen to a different antibody which has the same specificity as the first one, but does not have the same biological function. In a different situation, a hapten may be used to prevent the reaction of an antibody with its intended antigen. This is referred to as the hapten inhibition test. An example would be blood group substance soluble molecules equivalent to erythrocyte surface isoantigen epitopes found in the body fluids. Refer to ABO blood group substances.

# blood group

The classification of erythrocytes based on their surface isoantigens. Among the well-known human blood groups are the ABO, Rh, and MNS systems.

#### blot

The transfer of DNA, RNA, or protein molecules from an electrophoretic gel to a nitrocellulose or nylon membrane by osmosis or vacuum, followed by immersing the membrane in a solution containing a complementary, i.e., mirror-image molecule corresponding to the one on the membrane. This is known as a hybridization blot.

## Bombay phenotype

The O<sub>h</sub> phenotype is an ABO blood group antigen variant on human erythrocytes in rare subjects. These red blood cells do not possess A, B, or H antigens on their surfaces, even though the subject does have anti-A, anti-B, and anti-H antibodies in the serum. The Bombay phenotype may cause difficulties in crossmatching for transfusion.

#### bombesin

A neuropeptide of 14 residues that is analogous to a gastrinreleasing peptide that is synthesized in the gastrointestinal tract and